

Supplemental Amendment - Following Suspension Of Action Under 37 C.F.R. §1.103(c)
Application No. 10/511,725
Attorney Docket No. 042872

REMARKS

Claims 1-29 are currently pending.

I. The Request for Suspension of Action under 37 C.F.R. § 1.103(c)

A Request for Suspension of Action under 37 C.F.R. § 1.103(c) of three months was filed together with the RCE and Amendment under 37 C.F.R. § 1.114 filed July 2, 2007. The USPTO procedures were followed by requesting the Suspension of Action on the RCE Transmittal Form PTO/SB/30.

The Restriction Requirement dated September 24, 2007 was mailed prior to the end of the requested period for suspension.

II. The 132 Declaration and the Compositions of Omori

The Examiner is requested to consider the amendment and comments in the Amendment under 37 C.F.R. § 1.114 filed July 2, 2007.

Further, during the Interview dated June 14, 2007, Examiner Clark recommended that Applicants submit a 132 Declaration to establish the amount of components in the compositions of Omori et al. The 132 Declaration filed concurrently herewith establishes the compositions of Omori are outside the claimed invention in multiple characteristics.

III. Conclusion

In view of the above and in view of the amendment and comments in the Amendment under 37 C.F.R. § 1.114 filed July 2, 2007, Applicants respectfully submit that their claimed invention is allowable and ask that the rejections under 35 U.S.C. §112 and the rejections under

Supplemental Amendment - Following Suspension Of Action Under 37 C.F.R. §1.103(c)
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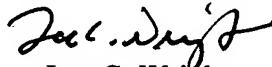
35 U.S.C. §§102 and 103 be reconsidered and withdrawn. Applicants respectfully submit that this case is in condition for allowance and allowance is respectfully solicited.

If any points remain at issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the local exchange number listed below.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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LCW/af

Enclosure: Declaration under 37 C.F.R. § 1.132
Amendment Transmittal (for excess claims)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Toshiro OMORI et al.**

Group Art Unit: **1655**

Application Number: **10/511,725**

Examiner: **Amy Lynn Clark**

Filed: **October 19, 2004**

Confirmation Number: **2520**

For: **COMPOSITION OBTAINED FROM BARLEY SHOCHU STILLAGE AND
HAVING ACTIVITY OF INHIBITING ONSET OF ALCOHOLOC
HEPATOPATHY AND ACTIVITY OF HEALING IT AS WELL AS
EXCELLENT PALATABILITY, AND PROCESS FOR PRODUCING THE SAME**

Attorney Docket Number: **042872**
Customer Number: **38834**

DECLARATION UNDER 37 C.F.R. §1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Toshiro OMORI, currently residing at 704-4 Oaza Kuzuhara Usa-shi Oita, Japan,
declare as follows:

1. On March, 1985 I graduated from Kyushu University Agricultural Department, faculty of
Agricultural Chemistry,

On April 1985 I joined the Sanwa Shurui Co., Ltd.,

From April 1989 to December 1989 I was a Trainee at National Tax Administration
Agency's brewing laboratory,

On March 1995 I received a Ph.D. degree in Agriculture from Kyushu University,

Declaration Under 37 C.F.R. §1.132

Application Number: 10/511,725

Page 2

From October 1996 to April 1998 I was a visiting Fellow at University of California Davis,

On April 1998 I was the General Manager of Laboratory Department at Sanwa Shurui Co., Ltd.,

On April 1999 I was the Deputy General Director of Laboratory at Sanwa Shurui Co., Ltd.,

On January 2001 I was CEO of Barley Fermentation Technologies, Inc.,

October 2003 I was Director of Laboratory at Sanwa Shurui Co., Ltd., and

In 1995 I received the Brewing Society of Japan's "Technology Award";

2. I am familiar with the prosecution of the present U.S. Patent Application;
3. I have reviewed and am familiar with Japanese Published Unexamined Application 2004-145472 to Omori et al (hereinafter "Omori '472"). I (Omori) am the first named inventor of Omori '472;
4. The numerical values of the data listed on pages 32-33 of the present specification are based on experiments I conducted;
5. The present specification describes Omori '472 as follows:

By the way, the ethanol-insoluble fraction described in document 4 [Omori '472] is obtained by a method which is entirely different from the method of obtaining the unadsorbed fraction by subjecting the liquid fraction of the barley *shochu* stillage (liquid fraction obtained by subjecting the barley *shochu* stillage to liquid-solid separation) to the separation treatment by adsorption using the synthetic adsorbent in the invention.

Declaration Under 37 C.F.R. §1.132

Application Number: 10/511,725

Page 3

That is, the ethanol-insoluble fraction described in document 4 [Omori '472] is formed by adding an alkali to the liquid fraction of the barley *shochu* stillage to obtain an alkali-soluble fraction, neutralizing the alkali-soluble fraction with an acid to obtain a neutral soluble fraction and adding ethanol to the neutral soluble fraction for precipitation. The ethanol-insoluble fraction contains 28 ± 3 % by weight of hemicellulose as one of main components, and this hemicellulose has a saccharide composition of from 60 to 70% by weight of xylose. (The present application, pages 11-12) (Emphasis added).

6. The present specification further states:

Meanwhile, the unabsorbed fraction of the invention [of the present application] contains the plural peptides having the average chain length of from 3.0 to 5.0, which are not described at all in document 4 [Omori '472]. Although the unadsorbed fraction of the invention [of the present application] contains from 15 to 25% by weight of polysaccharides (which will be described later), the saccharide composition of the polysaccharides is no doubt different from that of the hemicellulose. Accordingly, the ethanol-insoluble fraction described in document 4 [Omori '472] is clearly different from the unadsorbed fraction of the invention [of the present application]. (The present application, page 12);

7. The composition of Omori '472 is a composition that is produced by the method of using barley as the basic ingredient of a *shochu* production, carrying out solid-liquid separation of the barley *shochu* stillage, produced as an accessory component, and liquid is obtained; adding alkali to this liquid and batching off alkali soluble fraction; neutralizing this alkali soluble fraction with

Declaration Under 37 C.F.R. §1.132

Application Number: 10/511,725

Page 4

acid to obtain neutral soluble fraction; and obtaining fraction that is precipitated when ethanol is added to this neutral soluble fraction. This composition consists of 32 to 38% organic acid, 28 to 34% protein, and 25 to 31 % hemicellulose.

8. The data mentioned in the specification of the present application was obtained based on experiments conducted by myself, under my supervision and control or at my direction and is accurate;

9. The following experiment was conducted by myself, under my supervision or at my direction;

10. A liquid fraction composition made according to the disclosure Omori '472 was tested and the data is shown in TABLE 1 below:

TABLE 1

		Compositions of Present Application		Composition of Omori (JP2001-145472)
	disclosure	measured value	measured value	
average chain length of peptide (protein)	3.0~5.0	4.2	7.4*	
total amino acid derived from peptide	8~14%	9.8%	33.1%*	
amino acid content when total amino acid originating from peptide makes 100%	glutamic acid glycine aspartic acid proline serine	24~38% 4~20% 5~10% 4~9% 4~8%	34.7% 5.2% 8.3% 7.9% 5.7%	26.7% 8.1% 11.7% 5.7% 7.6%
total content of free sugar		5~10%	9.3%	3.4%*
percentage of free sugar	xylose arabinose	0.5~5% 0.5~3%	2.2% 1.7%	0.05%* 0.03%*
total content of polysaccharide		15~25%	17.6%	29.2%*
percentage of sugar constituting polysaccharide	glucose xylose arabinose	6~16% 3~12% 0.5~4%	14.3% 10.8% 3.4%	4.4%* 19.4%* 5.8%*
Molecular weight distribution of the composition			See Sample 2 in attached MW material	See Sample 4 in attached MW material
				* value outside of the scope of present invention

Declaration Under 37 C.F.R. §1.132

Application Number: 10/511,725

Page 6

11. The molecular weight distribution of samples of TABLE 1 was also measured; Molecular weight distribution was measured by Size-Exclusion Chromatography (SEC) using TSKgel G3000PW_{XL} column;

12. The results of the molecular weight measurement for each composition are shown in TABLE 2 below and in the attached chromatograms. Experiment 2 of TABLE 2 and the chromatogram of Experiment 2 corresponds to the inventive sample shown in TABLE 1 and Experiment 4 of TABLE 2 and the chromatogram of Experiment 4 corresponds to the composition representative of Omori '472 shown in TABLE 1;

TABLE 2 Result of Molecular Weight Measurement

Scope of molecular Weight	Peak Area in Percentage (%)			
	Experiment 1)	2)	3)	4)
More than 100,000	Minimal	Minimal	2	1
30,000~100,000	1	1	6	3
10,000~30,000	1	Minimal	9	5
3,000~10,000	3	1	19	11
1,000~3,000	23	22	23	37
500~1,000	17	17	13	12
Less than 500	55	59	28	31
Total	100	100	100	100

Declaration Under 37 C.F.R. §1.132

Application Number: 10/511,725

Page 7

13. The present invention condenses relatively short chained peptides, amino acid and polysaccharides, etc. with an average chain length of 3 to 5 within barley shochu stillage, and obtains a composition with a balance as claimed as an objective. Further, the composition of the present invention is obtained by use of synthetic adsorption after liquid-solid separation as claimed;

14. On the other hand, Omori '472 can be said to have been processed with alkali in order to solubilize insoluble hemicellulose that exists within barley shochu stillage, and having the objective of condensing and extracting polysaccharides (especially hemicellulose) having relatively large molecular weight and protein etc., and causing precipitation process with ethanol;

15. Omori '472 makes the shochu stillage their starting composition, so with the effect of enzymatic degradation of aspergillus and yeast etc. within the shochu manufacturing process, the molecular weight of the composition is low-molecularized to some extent, but, within that, the objective is to collect the elements with relatively large molecular weight that precipitates with the addition of alcohol.

16. Therefore, the objective of the process of manufacture is different between the invention of the present application and that of Omori '472;

17. The composition that produced by Omori '472 and the claimed composition is also different;

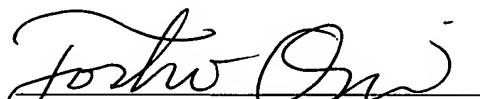
18. As can be seen from the last column of data in the TABLE 1, the composition made by a process representative of Omori '472 is outside the scope of the claimed characteristics in ten

Declaration Under 37 C.F.R. §1.132
Application Number: 10/511,725
Page 8

characteristics.

19. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: This 1st day of November, 2007



[signature]
Toshiro OMORI

Attachments: 2 Chromatograms